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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,493	03/26/2007	Akiko Nishimura	2520-0133PUS1	3828

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EXAMINER
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SASAKI, SHOGO

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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02/06/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,493	<b>Applicant(s)</b> NISHIMURA ET AL.	
	<b>Examiner</b> Shogo Sasaki	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4 and 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-5 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/2/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/16/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of laminated/layered multi-well plates with different configurations are as follows:

Species A, as claimed in claim 2 (Fig. 2).

Species B, as claimed in claim 3 (Fig. 3).

Species C, as claimed in claim 4 (Fig. 4).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim is generic: Claim 1.

2. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species have mutually exclusive characteristics, as shown by the above cited figures. In addition, these species are not obvious variant of each other based on the current record.

3. During a telephone conversation with Mr. Toyohiko Konno on 1/28/2009, a provisional election was made to prosecute the invention of Species C, claim 4. Affirmation of this election must be made by applicant in replying to this Office action.

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Claims 2 and 3 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 4 recites the limitation "the bottom sheet," "the spacer sheet" and "the coversheet." There is insufficient antecedent basis for these limitations in the claim. It is suggested to replace "the bottom sheet," "the spacer sheet" and "the coversheet" with "a bottom sheet," "a spacer sheet" and "a coversheet," or to define a bottom sheet, a spacer sheet and a coversheet, earlier in the claim. It is also suggested to modify said claim to read "The multi-well plate according to claim 1, wherein said sheets comprising: (a) a bottom sheet; (b) a spacer sheet ...; and (c) a spacer sheet ..., wherein ..." (As recited so in claims 2 and 3).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over McPherson et al. (US 5096676).

Regarding claims 1, 4 and 5, McPherson et al. disclose a multi-well plate (Fig. 1) comprising a multi-well tray (12) including wells (20); and a coversheet (34) having an adhesive material on the lower surface which is in sealable engagement with the multi-well tray (column 4, lines 3-7). The wells include porous liquid absorbing materials (Fig. 5 and 6, 44) which are held by a cylindrical column (28) and the wall of the well (column 5, lines 30-68).

The multi-well tray (Fig. 1, 12) of McPherson et al. is of a single piece construction. McPherson et al. do not teach that the bottom portion of the tray and the upper portion comprising the wells can be constructed by laminating/fusing/bonding said two portions. The tray of McPherson et al. including the side walls, the end walls, the wells and the columns are all integrally formed by an injection molding process from a clear moldable plastic such as polystyrene (column 4, lines 17-19).

Applicant discloses that the bottom and the spacer sheet may be of same material, such as polystyrene (page 5, lines 18-20; and page 6, lines 19-20). Therefore the laminated body comprising the bottom and the spacer sheet will be a single piece once they are laminated/fused/bonded.

It would have been obvious to one having ordinary skill in the art at the time of the invention to make the multi-well tray of McPherson et al. from two pieces. One of ordinary skill in the art at the time the invention was made would have been motivated to manufacture a multi-well tray by bonding a bottom sheet with a sheet with multiple apertures, for the purpose of avoiding the use of complex molding machine to form the wells. Skilled artisan would have been led by the prior art to forgo use of separate modules to reduce the manufacturing complexity and cost.

McPherson et al. also do not explicitly disclose that said multi-well plate is sealed inside a packing container.

However, the device will have to be shipped to the end user, and the packaging will have to be provided. It would have been obvious to one having ordinary skill in the art at the time of the invention to place a product in a sealed packing container, for the purpose of preventing contamination. The claim would have been obvious because “a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.”

12. Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wicks et al. (US 5958675).

Regarding claims 1, 4 and 5, Wicks et al. disclose a device (Petri-film type) for bacterial detection and growth (Fig. 1; and column 5, lines 14-21). The device (10) includes: a bottom sheet having a water-proof surface (12); a spacer layer (20) with an aperture; a cover layer; and a hydratable dry powder layer (16) sandwiched and fixed in place by the bottom sheet and the spacer layer (column 8, lines 2—44; column 9, lines 55-61; and column 12, lines 21-49). Wicks et al. also state that the similar device (Petri-plate) including multi-well culture compartment is well known in the art (column 8, lines 8-12).

It would have been obvious to one having ordinary skill in the art at the time of the invention to make multiple culture compartments on said device, since mere duplication of essential working parts of device involves only routine skill in the art.

Wicks et al. also do not explicitly disclose that said multi-well plate is sealed inside a packing container.

However, the device will have to be shipped to the end user, and the packaging will have to be provided. It would have been obvious to one having ordinary skill in the art at the time of the invention to place a product in a sealed packing container, for the purpose of preventing contamination. The claim would have been obvious because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."

### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Brian R Gordon/

Primary Examiner, Art Unit 1797